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EXAMINER	
WHALEY, PABLO S	
ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,522	LURIE ET AL.	
	Examiner	Art Unit	
	PABLO WHALEY	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/31/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 07/27/2010, have been fully considered.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1-50 are currently pending and under consideration. Claim 51 is cancelled.

Information Disclosure Statement

The information disclosure statement filed 08/31/2010 has been considered in full.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

This rejection is newly applied.

Claims 1-11, 28-36, 45-50 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons.

The instant claims are directed to a computer-readable medium holding instructions executable in a computing device, the instructions, when executed, causing

a computing device to perform a process. The disclosure provides examples of physical embodiments of signal bearing media [Specification, page 44]. However, the disclosure does not supply a limiting definition of computer-readable media and therefore is not sufficient to distinguish a computer-readable medium from a signal. Therefore the claims cover both transitory and non-transitory embodiments, and are non-statutory.

The USPTO recognizes that applicants may have claims directed to computer readable media that cover signals per se, which the USPTO must reject under 35 U.S.C. § 101 as covering both non-statutory subject matter and statutory subject matter. In an effort to assist the patent community in overcoming a rejection or potential rejection under 35 U.S.C. § 101 in this situation, the USPTO suggests the following approach. A claim drawn to such a computer readable medium that covers both transitory and non-transitory embodiments may be amended to narrow the claim to cover only statutory embodiments to avoid a rejection under 35 U.S.C. § 101 by adding the limitation "non-transitory" to the claim (e.g. a non-transitory computer readable medium). Such an amendment would typically not raise the issue of new matter, even when the specification is silent because the broadest reasonable interpretation relies on the ordinary and customary meaning that includes signals per se. The limited situations in which such an amendment could raise issues of new matter occur, for example, when the specification does not support a non-transitory embodiment because a signal per se is the only viable embodiment such that the amended claim is impermissibly broadened beyond the supporting disclosure. See, e.g., Gentry Gallery, Inc. v. Berkline Corp., 134

F.3d 1473 (Fed. Cir. 1998). The applicants are cautioned against introduction of new matter in an amendment.

Claim rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
>
> The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Claims 1-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims that depend directly or indirectly from claims 1, 12, 22, 28, 37, and 45 are also rejected due to said dependency.

This rejection is necessitated by amendment.

Regarding claims 1, 12, 22, 28, 37, and 45: The claims recite "persistently storing a simulation context...by registering an area of memory..., the persistently storing making the simulation context available after the simulation finishes so that the

simulation may be restored to a state consistent with the simulation context." This limitation is unclear for two reasons.

(1) It appears that "persistently" storing results in two different functional limitations (e.g. registering of memory and making the simulation context available after the simulation finishes). The specification does not provide a limiting definition for "persistently" storing data such that the technical scope of this limitation is well defined. Therefore it is unclear what limitation of the claimed method is intended by "persistently" storing a simulation context.

(2) It is unclear what limitation of the claimed process is intended by "...so that the simulation may be restored to a state consistent with the simulation context." Is this an active method step (e.g. restoring the simulation...), a limitation of how the simulation context is stored, or an intended use?

This rejection could be overcome, for example, by amending the claims to delete the term "persistently" and include positive limitations such as (1) storing persistent data of a simulation...by registering an area of memory,..., and (2) making the simulation context available to the simulation engine after the simulation finishes.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

This is a NEW MATTER rejection.

Regarding claims 1, 12, 22, 28, 37, and 45: The claims have been amended to recite "persistently store a simulation by registering an area of memory" and "persistently storing a simulation by registering an area of memory." Applicant's remarks do not point to specific support for these limitations. No support for the term "persistently" storing a simulation has been found in the specification, drawings, or claims of the application as originally. Therefore the claims are rejected for reciting new matter. This rejection is necessitated by applicant's amendments filed 07/27/2010.

Claim Rejections - 35 USC § 103

Response to Arguments

Applicant's arguments, filed 7/27/2010, that Lett does not teach persistently storing a simulation context to make the simulation context available after the simulation finishes so that the simulation may be restored to a state consistent with the simulation context, as recited in the present independent claims are persuasive. The rejection of claims 1-50 as being unpatentable over Lett, Fox, and Potts under 35 USC 103(a) has been withdrawn in view of the amendments to the claims. However, a new ground(s) of rejection is made in view of applicant's amendment.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5-14, 16-23, 25-30, 32-36 are rejected under 35 U.S.C. 103(a) as being made obvious by Lett et al. (WO 02/099736; Published 12 December, 2002; IDS filed 11/08/2004), in view of Beckerle et al. (US 6311265; Issued: October 30, 2001), and in

view of Cook (The Design of a Simulation System for Persistent Object Storage Management; University of Colorado; March 1993; p.1-23).

This rejection is necessitated by amendment.

The claims are drawn to a method, system, and computer-readable medium holding instructions executable in a computing device, the instructions when executed causing at least one computing device to:

(1) generate a result from executing a block diagram model of a biological process by performing a simulation of the block diagram model with a simulation engine;

(2) persistently store a simulation context of the simulation by registering an area of memory that constitutes the simulation context, the simulation context comprising one or more values for one or more attributes, the one or more values being established during the simulation of the block diagram model, the persistently storing making the simulation context available after the simulation finishes so that the simulation may be restored to a state consistent with the simulation context;

(3) gather data directly from an in situ experimental device on which an ongoing in situ experiment of the biological process is conducted;

(4) compare the generated result to the data gathered from the experimental device using an analysis environment that is in communication with the simulation engine; and

(5) modify the model of the biological process based on the comparison to correct the model of the biological process.

Lett teaches a computational method and system for incorporating image data into a biological simulation model [p.10-12]. In particular, time-series images of biological samples are obtained from experimental imagers [p.11-12], which is interpreted as gathering data from an in-situ experimental device since the data is obtained over time. The acquired image data is transmitted to a computer comprised of a central processing unit (CPU), a user interface, and memory (including both primary random access memory and nonvolatile secondary memory [p.12 and Fig. 1]. A simulation program generates predicted images, and these generated images are compared with acquired images [p.14]. The simulation model is then modified to improve the goodness of fit between predicted and obtained images [See at least p.14, last ¶, and p.24], which shows a modifying a model based on a comparison to correct the model. In particular, numerical intensity values are used to compare images [p.15], which is a teaching for values established during a simulation context. The simulation model is described according to a block diagram and is used to predict spatial distribution variables [See at least p.22 and Fig. 2], therefore Lett teaches an analysis environment for generating results according to a block diagram model. Image data can be obtained from a gene-chip and microarray data [Ref. claims 18, 19, and p.18]. The simulation model includes program code for performing the simulations [p.37]. Lett teaches calculating error measures that correlate with the difference between the

predicted and acquired images are calculated [p.17]. Lett teaches a display for displaying simulation results to a user [See at least Fig. 1 and 2]. Regarding limitations directed to the simulation context comprising values that are established during the simulation of the block diagram model, Lett shows feedback loops and calculating variables throughout the simulation process [See e.g. p.11-12, 22, and 36]. Therefore Lett implicitly teaches limitations directed to storing a simulation context during the simulation of a block diagram model.

Lett does not teach storing persistent data of a simulation by registering an area of memory that constitutes the simulation context, the persistently storing making the simulation context available after the simulation finishes so that the simulation may be restored, as in claims 1, 12, 22, and 28.

Cook teaches a simulation system for persistent data storing management. Cook describes simulation system architecture and modules for memory allocation and memory registration to physical locations [Section 3.1, p.6-7, and Table 1]. Cook also describes a persistent data interaction process that includes reading memory, performing simulation, and passing the data with changes back to the persistent data system for the benefit of obtaining persistence (i.e. consistency) and improving overall efficiency [Section 3.3, p.10].

Beckerle teaches apparatuses and methods for programming parallel computers. The invention includes the storing of persistent data sets that exist on permanent disk storage, before or after the execution of the simulation process [See e.g. Col. 8, ¶2, ¶3].

Beckerle also discusses a repeatedly storing and reading data to a disk [Col. 44, lines 1-50].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to have modified the method, program, and system of Lett, by persistently storing simulation data by registering an area of memory and making the data available after the simulation finishes, as taught by Cook [Section 3.3, p.10], since Cook and Beckerle show that persistent storing techniques would have been predictable to one of ordinary skill in the art. The motivation would have been to use a system architecture that beneficially improves performance through persistence, as suggested by Cook, or to have taken advantage of the power of parallel processing for performing simulations, as suggested by Beckerle [Col. 1].

Claims 4, 15, 24, 31, and 37-50 are rejected under 35 U.S.C. 103(a) as being made obvious by Lett et al. (WO 02/099736; Published 12 December, 2002; IDS filed 11/08/2004), in view of Cook (The Design of a Simulation System for Persistent Object Storage Management; University of Colorado; March 1993; p.1-23), and in view of Beckerle et al. (US 6311265; Issued: October 30, 2001), as applied to claims 1-3, 5-14, 16-23, 25-30, 32-36, above, and further in view of Fox et al. (WO 03/042857, Published 22 May 2003; IDS filed 11/08/2004), and in view of Potts et al. (US 6,882,940; Filed Aug. 10, 2001).

Lett, Cook, and Beckerle make obvious a method, program, and system for simulating biological processes using a block diagram simulation model, as set forth above. Additionally, Lett teaches a display for displaying simulation results to a user [See at least Fig. 1 and 2], as in claim 46.

Lett, Cook, and Beckerle do not teach modifying a model of a biological process wherein the process is a chemical reaction, as in claims 37-39, 41-45, and 48-50.

Lett, Cook, and Beckerle do not teach generating an event signal when the difference between the result and data gathered from the device exceeds a threshold, as in claims 4, 15, 24, 31, 40, and 47.

Fox teaches a method and system for inferring biochemical interaction networks including chemical reactions from dynamical or static experimental data, and a database of possible interactions [0065]. The simulation process operates according to a block diagram and includes the use of threshold values [Fig. 7, Fig. 8].

Potts teaches a prediction system with a modeling environment that allows for user-settable threshold levels [Col. 13, lines 20-25] and functionality for generating an alert signal when a measured signal is outside of the predetermined range of values [Co. 7, lines 20-23].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to have alternatively modeled a chemical reaction, as taught by Fox, using the method, program, and system made obvious by Lett, Cook, and Beckerle, with a reasonable expectation of success, since Lett suggests biological modeling software that models chemical reactions using experimental microscopic

image data with predictable results [p.5, and p.7-9], and since Fox specifically employs a block diagram for simulating chemical reactions from experimental data [0065, Fig. 7, Fig. 8]. The motivation would have been to predict new interactions for the biological system being studied, as suggested by Fox [Abstract].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to have generated an event signal when the difference between the result and data gathered from the device exceeds a threshold, using the method, program, and system made obvious by Lett, Cook, and Beckerle, with a reasonable expectation of success, since Fox suggests the use of thresholds in a block diagram simulation process with predictable results, as set forth above, and since Potts employs software programming for generating an alert signals when signals are outside of threshold ranges with predictable results [Co. 7, lines 20-23]. The motivation would have been to improve simulation by generating warning messages when there are images with statistical differences between them, as suggested by Lett [p.15].

Provisional Obviousness-Type Double Patenting Rejection

Response to Arguments

Applicant's statement, filed 7/27/2010, that a terminal disclaimer will be filed if needed is acknowledged but is not persuasive as no such disclaimer has yet been filed. This rejection has been modified in view of applicant's amendment.

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

The conclusion of obviousness-type double patenting is made in light of these factual determinations. Any obviousness-type double patenting rejection should make clear: (A) The differences between the inventions defined by the conflicting claims; and (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue is anticipated by, or would have been an obvious variation of , the invention defined in a claim in the patent.

Claims 1, 12, 22, and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 3 of copending Application No. 10/783552 in view of Lett and Cook. The differences between the inventions defined by the conflicting claims are as follows: the copending claims are drawn to simulations that are a species of the instant claims, wherein the species “chemical reactions” are a species of biological process. Furthermore, the copending claims do not recite persistently storing a simulation context by registering an area of memory that constitutes the simulation context, wherein the simulation context is made available after the simulation finishes. However, a person of ordinary skill in the art would conclude that the invention defined in the instant claims at issue would have been an obvious variation of the claims of the cited copending application in view of the

teachings of Lett, Cook, and Beckerle, since Cook and Beckerle show that persistent storing techniques would have been predictable to one of ordinary skill in the art. The motivation would have been to improve system efficiency using a system that provides the added benefit of obtaining persistence, as suggested by Cook. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached between 12pm-8pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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